DLA Piper LLP (US)
1251 Avenue of the Americas
27th Floor
New York, New York 10020-1104
www.dlapiper.com

Loren H. Brown
loren.brown@us.dlapiper.com
T 212.335.4846
F 212.884.8546

May 30, 2025

VIA ECF

MEMO ENDORSED

Hon. Katherine Polk Failla
Thurgood Marshall
United States Courthouse
40 Foley Square
New York, NY 10007

Re: ***In re: Chantix (Varenicline) Mktg., Sales Practices and Prods. Liab. Litigation (No. II)*** **22-MD-3050 (KPF), 22-mc-3050 (KPF) (S.D.N.Y.)**

Dear Judge Failla:

Pursuant to Section 9 of the Court's Individual Rules of Practice in Civil Cases, Pfizer respectfully submits this letter motion requesting an order granting leave to file under seal Pfizer Exhibits 1, 2, 6, 7, and 8 attached to the parties' May 30, 2025, joint letter. Within the joint letter, Pfizer requested the Court's permission to file an early motion for summary judgment and, in support, attached exhibits. Pfizer had designated certain documents among the exhibits "Confidential" under the operative protective order when producing them in discovery and Plaintiffs did not challenge the designations. (*See* ECF No. 67 at II.C., II.H.) As these documents contain competitively sensitive business and trade secret information, Pfizer requests they remain under seal on the Court's docket. (*Id.* at VI.B., X.; Indiv. R. Prac. Civ. Cases, Failla, J. § 9.B.-C., S.D.N.Y. (rev. Jan. 3, 2025).)

I. THE CONFIDENTIAL EXHIBITS PFIZER REQUESTS TO SEAL

Pfizer requests leave to file Exhibits 1, 2, 6, 7, and 8 under seal:[1]

- **Exhibit 1** is Pfizer's internal report dated August 3, 2021, on the root cause investigation Pfizer conducted regarding the cause of nitrosamine in Chantix. Exhibit 1 contains proprietary information on Chantix, its active pharmaceutical ingredient, its excipients, its

[1] Pfizer does not seek to seal Exhibits 3, 4, or 5. Exhibit 3 is the publicly available Chantix approval letter from FDA's website; Exhibit 4 is a portion of the Chantix Chemistry Review as shown on FDA's website, which includes FDA's redactions and withholdings due to "Trade Secret/Confidential" information (*see generally* Ex. 4); and Exhibit 5 is FDA's 2020 Guidance for Industry on the Control of Nitrosamine Impurities in Human Drugs.

- composition, batch testing, stability testing, supplier information, Pfizer's observations and conclusions, and reformulation and remediation strategies.

- **Exhibit 2** contains portions of the Chantix New Drug Application (NDA) Pfizer submitted to FDA on November 9, 2005. Exhibit 2 details the development of Chantix, Chantix components, specifications, testing, Pfizer's reasoning for certain actions, manufacturing processes, analytical procedures, justification for those procedures, and additional information specific to Pfizer and its drug development.

- **Exhibit 6** contains the April 30, 2021, NDA/ANDA Field Alert Report Pfizer provided to FDA regarding Chantix, including information from that and prior dates on Chantix testing, results of that testing, results of a toxicology evaluation, and additional testing and studies Pfizer would conduct.

- **Exhibit 7** contains a May 6, 2021, letter from FDA to Pfizer regarding FDA's evaluation of Chantix, its results, and requesting several categories of information from Pfizer about Chantix.

- **Exhibit 8** contains meeting minutes from an August 1, 2022, meeting between Pfizer and FDA, the objective of which was to discuss Chantix remediation. This Exhibit includes several questions from Pfizer on Chantix remediation and reformulation, FDA's feedback, Pfizer's responses to FDA's feedback, and discussions at the meeting on these topics, such as composition and considerations on the same, and related topics germane to Chantix formulation.

II. DISCUSSION

While there is a common law presumption in favor of permitting public access to judicial documents, a court balances this presumption of access against competing comparisons, including "the privacy interests of those resisting disclosure." *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 120 (2d Cir. 2006) (quoting *United States v. Amodeo*, 71 F.3d 1044, 1050 (2d Cir. 1995)). Competitively sensitive information, for example, should be protected against public disclosure if such disclosure would cause significant and irreparable competitive injury. *See, e.g.*, *Standard Inv. Chartered, Inc. v. Fin. Indus. Reg. Auth.*, 347 F. App'x 615, 617 (2d Cir. 2009).

Here, Pfizer narrowly tailored its request to seal only exhibits that contain direct sensitive, confidential business information and trade secrets. As part of FDA's oversight, Pfizer and FDA have confidential, non-public communications about Pfizer's pharmaceutical products, including information that informs Pfizer's business strategy. Pfizer's exhibits are in the context of the highly

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competitive and regulated pharmaceutical space and relate to FDA's regulatory control and monitoring. (*See* Exs. 1-2, 6-8.) Pfizer detailed to FDA exacting information about Chantix's development, specifications, testing, and remediation, but this information was never intended for public disclosure and Pfizer would suffer irreparable competitive injury if this information were not sealed.

Courts routinely recognize the commercially sensitive nature of the exact type of information Pfizer now seeks to seal. *See, e.g.*, *Life Spine, Inc. v. Aegis Spine, Inc.*, No. 19 CV 7092, 2022 WL 1307111, at *3 (N.D. Ill. May 2, 2022) (allowing product research, information, and FDA submissions to remain under seal); *Kaleo, Inc. v. Adamis Pharms. Corp.*, No. CR 19-917-RGA, 2019 WL 11680196, at *1 (D. Del. July 16, 2019) (sealing "details of, discussion of, and/or reference to confidential communications with FDA" because disclosure "would cause a clearly defined and serious injury"); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 217CV05914SRCCLW, 2018 WL 10152220, at *2 (D.N.J. Nov. 13, 2018) (sealing "communications with the FDA about NDA No. 209-764, and Merck's plans relating to that NDA" because disclosure would cause "serious injury to Merck"); *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, No. 1:15-CV-00369-RMB-JS, 2017 WL 11634622, at *1 (D.N.J. Aug. 28, 2017) (sealing pharmaceutical company's materials concerning drug application, proprietary testing, ingredients, product formulation and manufacture, research and development, and "commercially sensitive communications with the FDA" on the product). Just as those courts have held, Pfizer respectfully requests the Court seal its exhibits here, protecting Pfizer from the irreparable competitive harm if these confidential documents were made public.

III. CONCLUSION

Pfizer respectfully requests that the Court enter an order sealing Pfizer Exhibits 1, 2, 6, 7, and 8 to the parties' May 30, 2025, joint letter.

Respectfully,

/s/ Loren H. Brown
Loren H. Brown
DLA PIPER LLP (US)
1251 Avenue of the Americas, 28th Floor
New York, NY 10020-1104
T: 212-335-4846
loren.brown@dlapiper.com

Counsel for Defendant Pfizer Inc.

cc: Counsel of Record (via ECF)

Application GRANTED. The Clerk of Court is directed to maintain docket entry 88 under seal, viewable to the Court and the parties only.

The Clerk of Court is further directed to terminate the pending motion at docket entry 87.

Dated: June 3, 2025
New York, New York

SO ORDERED.

HON. KATHERINE POLK FAILLA
UNITED STATES DISTRICT JUDGE